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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,138	03/17/2004	Beat Kilcher	HAWE-57-107	7117

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Donald F. Frei
Wood, Herron & Evans, L.L.P.
2700 Carew Tower
441 Vine Street
Cincinnati, OH 45202-2917

EXAMINER	
WERNER, JONATHAN S	

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,138	KILCHER ET AL.	
	Examiner	Art Unit	
	Jonathan Werner	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/23/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/23/04 was filed before the mailing of a first office action. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the use of "legal phraseology" in claim 1. Correction is required. See MPEP § 608.01(b).

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. ***Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading***. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitations "said mucosa pad" and "said lip portion" instead of reciting earlier references to "mucosa pads" and "lip portions" from claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3 and 4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims appear to recite part of the human body in combination with the structure of the claimed invention, "mucosa pads on the mucous membrane." It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 USC 101. The grant of limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). Applicant needs to clearly state using inferential language that the human

anatomy is not claimed. For examination purposes, the claims will be considered as if such limitations involving the combination with a human were not present.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Dorfman (US D496,995). In regard to claim 1, Dorfman discloses a dental retractor comprised of cheek portions and lip portions for the upper and lower lip. Figure 3 shows the lip portion of the retractor (bottom center) with the corresponding lip shield (bottom ridge) separately spaced apart from the mucosa pad (top ridge). Furthermore, figure 2 shows the cheek portions on the left and right sides and the lip portions on the top and bottom connected to each other by flexible connecting elements which are arranged between the lip shield and the mucosa pad. In regard to claim 2, figure 6 discloses the retractor's connecting elements arranged in a curved plane. In regard to claim 3, for the purpose of this rejection, the previously discussed non-statutory subject matter, "on the mucous membrane," is not taken into consideration and was stricken

from this analysis. However, figure 1 of Dorfman clearly shows the centerline of the lip shield and the point of support of the mucosa pad located at a distance away from each other. In regard to claim 6, figure 2 shows cheek portions that are connected to elements by a web since the applicant's specified structure is not described. In regard to claim 7, Dorfman's retractor has connecting elements designed and arranged so that the applicant's intended use is not given patentable weight since the lip portions would undergo translational movement when closing the mouth.

Additionally Claims 1-3 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Akihiro (US 6,203,471). In regard to claim 1, Akihiro discloses a dental retractor comprised of cheek portions and lip portions for the upper and lower lip. Figure 5 shows the lip portion of the retractor with the corresponding lip shield 2a separately spaced apart from the mucosa pad 2b. Furthermore, figure 5 shows the cheek portions 6 on the left and right sides and the lip portions 2 on the top and bottom connected to each other by flexible connecting elements which are arranged between the lip shield and the mucosa pad. In regard to claim 2, figure 8 discloses the retractor's connecting elements arranged in a curved plane. In regard to claim 3, for the purpose of this rejection, the previously discussed non-statutory subject matter, "on the mucous membrane," is not taken into consideration and was stricken from this analysis. However, figure 7 of Akihiro clearly shows the centerline of the lip shield and the point of support of the mucosa pad located at a distance away from each other. In regard to claim 6, figure 5 shows cheek portions that are connected to elements by a web since the applicant's specified structure is not described. In regard to claim 7, Akihiro's

retractor has connecting elements designed and arranged so that the applicant's intended use is not given patentable weight since the lip portions would undergo translational movement when closing the mouth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfman (US D496,995). Dorfman discloses a cheek and lip retractor that shows the limitations described above, however, the retractor does not show the distance from the lip shield to the mucosa pad to be between 10 mm and 30 mm. The claimed distance between the point of support of the mucosa pads and the centerline of the lip shield is between 10 mm and 30 mm. This distance represents the approximate thickness of an individual's lips. Therefore, it would have been obvious to a person having ordinary skill in the art to make the distance between the mucosa pads and the lip shield between 10 mm and 30 mm in order to properly ensure that the dentist has enough room to treat the front of the outside teeth region including the gingival tissue located therein.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfman in view of Leal (US 5,199,72). Dorfman discloses a mucosa pad without any type of cushioning for the gum region and Leal discloses a lip retractor (referred to in

specifications as a dental appliance) wherein portions of the frame are wrapped with a roll (figure 5) so as to "protect the soft tissue of the patient's mouth from the appliance" (col. 5, ln. 10). Additionally, Leal teaches that aside from rolls, any flexible material can be used on the appliance, and that the material can be removed and discarded after use. Therefore it would be obvious to one having ordinary skill in the art at the time of the invention to add removable mucosa pads to the lip portions of a retractor in order to cushion a patient's gums in view of Leal.

Additionally, Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akihiro (US 6,203,471). Akihiro discloses a cheek and lip retractor that shows the limitations described above, however, the retractor does not show the distance from the lip shield to the mucosa pad to be between 10 mm and 30 mm. The claimed distance between the point of support of the mucosa pads and the centerline of the lip shield is between 10 mm and 30 mm. This distance represents the approximate thickness of an individual's lips. Therefore, it would have been obvious to a person having ordinary skill in the art to make the distance between the mucosa pads and the lip shield between 10 mm and 30 mm in order to properly ensure that the dentist has enough room to treat the front of the outside teeth region including the gingival tissue located therein.

Lastly, claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akihiro in view of Leal (US 5,199,72). Akihiro discloses a mucosa pad without any type of cushioning for the gum region and Leal discloses a lip retractor (referred to in specifications as a dental appliance) wherein portions of the frame are wrapped with a roll (figure 5) so as to "protect the soft tissue of the patient's mouth from the appliance"

(col. 5, ln. 10). Additionally, Leal teaches that aside from rolls, any flexible material can be used on the appliance, and that the material can be removed and discarded after use. Therefore it would be obvious to one having ordinary skill in the art at the time of the invention to add removable mucosa pads to the lip portions of a retractor in order to cushion a patient's gums in view of Leal.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. O'Neill. (US 6,743,017) shows a mandibular inhibitor with corresponding cheek and lip portions connected by flexible connecting elements. Jones (US 1,742,080) shows a dental appliance with removable tubular mucosa pads. Jenkinson (US 4,889,490) shows a dental mask with corresponding cheek portions connected by flexible connecting elements. Horiguchi (US 6,500,002) shows a flexible oral cavity spreading apparatus with cheek portions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jonathan Werner
Examiner
AU 3732

JSW
7/27/05

MELBA N. BUMGARNER
PRIMARY EXAMINER